Quality Assurance
INFORMED CONSENT

I. Element of Informed Consent

A. Patient's medical condition

B. Proposed course of treatment

C. Risks and benefits of the proposed course of treatment and of non-treatment

D. Prospects for recovery

E. Significant alternative treatment

F. (Documentation of the patient's receipt of the information and consent to treatment, per policy)

II. Competent Adult

A. Adult

1. 18 years or older

2. Emancipated minors
   a. validly married
   b. active military duty
   c. in custody of law enforcement agency for routine nonsurgical medical care or emergency care without parent or guardian promptly located
   d. court ordered emancipation

3. Minors' exceptions
   a. substance abuse, venereal disease or HIV
   b. birth control information and devices
   c. mental health services
   d. abortion
   e. prenatal and pregnancy related health care
   f. blood donations (17 years of age or over)
   g. sterilization (Note: Medicaid prohibits under 21 years of age)
B. Competency

1. Ability to understand the nature of one's disease and the proposed therapies.

2. Ability to understand potential consequence of refusing these therapies.

3. Ability to make and communicate his/her choice.

III. Legal Guardian

A. Documentation in the form of a copy of the "Letters of Authority" from the Probate Court, with the Court’s stamp and the judge’s signature on it.

B. The court order should be active.

C. The court order should encompass the power to consent for medical treatment.

IV. Patient Advocate

A. Documentation in the form of a Durable Power of Attorney for Health Care and Patient Advocate Acceptance Form.

B. Effective upon documented determination of incompetency by two (2) physicians or one (1) physician and a licensed psychologist and consultation with the patient advocate.

C. Ineffective upon regained patient competency.

D. May be revoked by the patient at any time, even during incompetency.

E. Spousal patient advocate designation suspended while an action is pending for separate maintenance, annulment or divorce and revoked upon judgement of same, unless the patient has named a successor to serve as patient advocate.

V. Next of Kin

A. In order of priority:

1. the spouse

2. an adult son or daughter

3. either parent

4. an adult sibling

VI. Guardianship
POLICY:
Only those patients who have voluntarily and knowingly consented to surgical and other intensive and/or invasive procedures shall receive those treatments at Beaumont Health System. Appropriate documentation of informed consent shall be required before commencing those treatments.

Informed consent is required, in general, when treatment is undertaken where a substantial risk of harm exists, where mandated by statute or by hospital policy or when treatment is of an experimental nature under the purview of Beaumont’s Human Investigation Committee.

No documentation of informed consent is required for routine care or non-invasive treatment that involves an insubstantial risk of harm to the patient because the patient has consented to such care upon signing the General Consent to Treatment form.

In the event of an emergency situation, this policy would not apply.

ELEMENTS OF INFORMED CONSENT

1. **Capacity:** The patient must have the capacity to consent. Capacity is determined by a physician. Competency is determined by a Court.

2. **Sufficient Information:** The patient must have sufficient information upon which to base the consent. This must include information about the patient’s medical condition; proposed and reasonable alternative treatments, including their risks, benefits, significant complications and side effects; the consequences of foregoing treatment; prospects for recovery; potential problems during recuperation and the likelihood of achieving the patient’s goals.

3. **Documentation:** The patient’s receipt of the information and consent to the treatment must be documented.

PROCESS FOR OBTAINING AND DOCUMENTING INFORMED CONSENT

1. **When the Process is Initiated in Physician’s Office**
   a. The physician must document in the office records that the patient has been given sufficient information concerning the proposed treatment, alternatives, risks, benefits, complications, prognosis and goals. Except where a specific consent form is required by statute, regulation or Hospital policy, a copy of the Physician’s documentation of informed consent need not be provided to the Hospital.
   b. If a specific consent form required by statute, regulation or Hospital policy is signed in the physician’s office prior to Hospitalization:
      • The patient must be admitted within the effective time frame if specified in the regulation, statute or Hospital policy, and
      • A copy of the specific consent form must be provided to the Hospital and in the Hospital medical record at the time of admission. (See Medicaid regulations for sterilization).
The patient must complete the Acknowledgment of Informed Consent ("Form #232") at the Hospital prior to the treatment. The patient’s signature must be witnessed by a treating physician, a nurse or a designated Hospital employee. The signed Form #232 is maintained in the Hospital medical record.

2. **When the Process is Initiated at the Hospital**
   a. If a specific consent form IS NOT required by statute, regulation or Hospital policy:
      - The attending physician or his/her designee must document in the Hospital medical record that he/she has discussed the proposed treatment, alternatives, risks, benefits, complications, prognosis and goals with the patient and that the patient consents to the treatment; and
      - The patient must sign the Form #232. The patient’s signature must be witnessed by a physician, a nurse or designated Hospital employee. The signed Form #232 is maintained in the Hospital medical record.
   b. If a specific consent form, other than the Form #232, IS required by Hospital policy, statute or regulation, for example, for sterilization, transfusions, or human investigation research:
      - The specific consent form must include the sufficient information upon which the patient’s consent is based and must document that the patient has consented. Specific consent forms must be approved in accordance with the Hospital policy on approval of new consent forms; and
      - The attending physician shall be available to discuss the content of the specific consent form with the patient; and
      - The patient must sign the specific consent form. The patient’s signature must be witnessed by a physician, nurse or designated Hospital employee. The signed specific consent form shall be made a part of the Hospital medical record.
      - Consent for transfusion of blood or blood products may be obtained by the ordering physician or that physician’s designee who may be a mid-level provider or nurse.

**RESPONSIBILITY FOR PROVIDING INFORMATION TO THE PATIENT**

1. **Physician**
   a. As a general rule, the physician performing the procedure or serving as the attending physician shall ensure that the patient has sufficient information about the procedure and that the appropriate documentation exists as to the informed consent procedure.
   b. In the event that a procedure involves administration of an anesthetic, the physician administering the anesthetic shall be responsible for ensuring that the patient has sufficient information regarding the anesthesia to be used during the procedure and for documenting that the information was given to the patient in accordance with the anesthesia consent.

2. **Health Care Worker**
   a. The health care worker may provide additional information to patients per Hospital policy.
   b. In general, if a patient requires additional information or displays confusion or hesitation about a scheduled treatment, it is the health care worker’s responsibility to notify the attending physician.
   c. If the attending physician fails to resolve the problem to the satisfaction of the reporting health care worker, the health care worker shall report the incident to his/her supervisor.
INFORMED CONSENT

Content Expert(s):
Legal Affairs

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d. If the attending physician fails to resolve the problem to the satisfaction of the supervisor, the supervisor shall report the incident to the Chairman of the Department. If the Chairman of the Department is unavailable, the supervisor shall report the incident to the Hospital Administrator and Medical Administrator on call. See Patient Care – Corporate Policy #312 – Patient Care Concerns/Chain of Command.

DOCUMENTATION REQUIREMENTS RELATED TO INFORMED CONSENT

1. With respect to Form #232, the role of the health care worker is to witness the signature of the patient, not the obtaining of informed consent.

2. All dates, times, and signatures must be in ink. If the signature is other than the patient’s, then the relationship of the signer to the patient should be noted below the signature.

3. In the event of a technical flaw in a specific consent form, the physician need not re-obtain the patient’s consent, but may proceed with the treatment after appropriate documentation in the medical record.

4. In general, the specific consent form remains effective for the duration of the hospitalization and is valid if:
   a. The nature or scope of the treatment, and the patient’s diagnosis, prognosis and medical condition is unchanged, and
   b. The patient or legal representative continues to demonstrate a willingness to undergo the treatment.

5. Where consent for a definite treatment is obtained pursuant to a court order, the consent is valid until the treatment has been accomplished.

6. Barriers to receipt of information and documentation of consent must be resolved.
   a. If a patient’s disability presents a barrier to communicating his/her understanding of the content and purpose of the Form #232, the law requires the use of special equipment and/or personnel to enable the disabled patient to give informed consent.
   b. If the patient or legal representative has a hearing disability, auxiliary aids, including a video phone and/or a relay service, or a qualified oral or sign language interpreter must be provided. See, Corporate Policy #315, “Interpreters for Deaf and Hard of Hearing Patients.”
   c. If the patient or legal representative has a visual impairment, the Physician or nurse should read the form to the patient or legal representative, and document that the reading took place.
   d. If the patient’s ability to speak, read, or understand English is limited, an interpreter must be provided. See, Corporate Policy #316, “Interpreters for Patients with Limited English Proficiency.”

EXCEPTIONS TO INFORMED CONSENT

1. Emergencies. In an emergency situation, the Physician must document the nature of the emergency and the reasons why he/she was unable to obtain written or verbal consent from the patient or the patient’s legally authorized representative. Consent is implied unless the physician or other health care worker has reason to know that the patient would not consent to the treatment, such as where there is an Advance Directive declining the treatment.
   a. Competent Adult

PATIENT CARE – CORPORATE POLICIES

Disclaimer: User must ensure that any printed copies of this policy/procedure are current by checking the policy/procedure web page before use.


i. Consent is implied where a patient is unconscious and unable to give his/her consent and immediate treatment is necessary to preserve the patient’s life or to prevent serious impairment of the patient’s health.

ii. Consent is implied not only in medical emergencies, but also for unanticipated events. A physician is justified in performing a procedure different from that which the patient agrees to when an unanticipated event or condition arises that is or may become life-threatening as a result of surgery or due to an unexpected complication discovered during surgery, and it is impractical or impossible to obtain the consent of the patient or one authorized to act in his/her behalf.

b. Incompetent Adult: Consent to treat an incompetent adult is implied in an emergency and attempts to obtain appointment of a legal guardian would delay treatment and cause permanent harm. If available, parents of an incompetent adult, who is incompetent from birth or becomes incompetent during minor years, may give consent.

c. Minors

i. Consent to treat a minor is presumed in an emergency just when attempts to reach the parents or legal guardian for consent would delay treatment and cause permanent harm.

ii. If the minor is not living at home, and does not have a legal guardian, consent should be implied in an emergency, where attempts to reach the Michigan Department of Human Services to obtain a legal guardian would delay treatment and cause harm to the patient.

iii. An abortion may be performed upon a minor in an emergency without a parent’s written consent or Court order waiving parental consent. An emergency is a situation in which continuation of the pregnancy would create an immediate threat and grave risk to the life of the minor, as certified in writing by a physician.

2. Therapeutic Privilege. If a psychiatrist chooses to withhold information from a patient based upon therapeutic privilege, he/she must document in the medical record his/her reasons for invoking such a privilege. By law, “therapeutic privilege” applies only to psychiatry.

3. Assumption of the Risk. The physician must document in the medical record any occurrence where the patient refuses to allow the physician to explain the risks, benefits, and reasonable alternatives of a proposed operation or medical intervention, but insists upon signing the written consent form. The physician should then have this discussion with a person authorized by the patient to hear this information and seek that person’s concurrence. The physician must also document when the patient orally consents to treatment.

4. Telephone Consent. Consent and authorization for treatment may be obtained by telephone if no reasonable opportunity to obtain written consent exists. The medical record should reflect who consented, the nature of the consent given, the date and time, and the names of two (2) witnesses to the obtaining of telephone consent.

5. Police Department.

a. If a police officer requests that a test be performed on a patient to determine the amount of alcohol or presence of a controlled substance, or both, in the patient’s blood, the police officer is responsible for obtaining written consent of the patient, or his/her representative (EC Form #2323). If the patient refuses to submit to the test, the Hospital shall honor the patient’s wishes and not proceed with the test unless the police officer obtains and presents a court order/search warrant.
b. Assuming a court order/search warrant has been obtained, the Hospital shall abide by it. The Hospital department in receipt of a court order/search warrant must refer to the Department of Legal Affairs before complying.

c. In the event that the patient becomes combative and refuses to remain at the Hospital, it is the police officer’s responsibility, not the Hospital’s, to restrain the patient.

6. **First Responders.** A First Responder who has either transported an emergency patient (the “Source Patient”) to the Hospital or assisted a Source Patient who is later transported to the Hospital for purposes of medical treatment may request that the Source Patient be tested for HIV and/or HBV if it is believed that the First Responder has sustained a percutaneous, mucous membrane or open wound exposure to the Source Patient’s blood or other body fluids. See EC Policy#312 – First Responder Exposure.

**WHO MAY CONSENT**

1. **Competent Adult.** A competent adult is one who is eighteen (18) years of age or older and can understand his/her medical condition, proposed treatment, alternatives, risks, benefits, complications, prognosis and goals.

   a. Before proceeding with treatment, the consent of a competent adult must be obtained. A competent adult has the right to refuse any treatment.

   b. An adult psychiatric patient is not presumed to be incompetent to consent to medical treatment. The patient’s psychiatrist and attending physician (if applicable) should make the determination as to whether the patient can understand his/her medical condition and proposed treatment. The determination should be documented in the medical record.

2. **Incompetent Adult.** An incompetent adult is one who, though eighteen (18) years of age or older, cannot understand his/her medical condition, proposed treatment, alternatives, risks, benefits, complications, prognosis and goals.

   a. An adult is presumed to be competent. If the treating physician questions whether the patient is competent, he/she should request the appropriate consultation, e.g., psychiatric or geriatric as appropriate to the patient’s condition/status. After consultation, the treating physician should assess whether the patient has sufficient capacity to make informed decisions regarding treatment and document that assessment in the medical record.

   b. If the treating physician concludes that the patient is not competent to give or refuse consent, treatment decisions may be made by one of the following surrogate decision makers:

      i. **Legal Guardian:** If a patient is declared incompetent by a Probate Court, consent of the court appointed guardian (“Legal Guardian”) is necessary for non-emergent medical/surgical treatment and, if readily available, for emergency treatment. The Legal Guardian may or may not be a family member and will have a Letter of Guardianship evidencing the appointment. Once appointed, only the Legal Guardian has authority to consent to or refuse medical/surgical treatment. If there is a difference of opinion between the family and the Legal Guardian, the Legal Guardian prevails. If there are any questions related to the Letter of Guardianship, please contact the Department of Legal Affairs. A copy of the Letter of Guardianship must be made part of the patient’s medical record.
**ii. Patient Advocate Acting Under a Durable Power of Attorney for Health Care:** A Durable Power of Attorney ("DPOA") is a written document by which a competent adult patient gives another adult the power to make medical treatment, psychiatric treatment and personal care decisions for the patient when the patient is unable to participate in treatment decisions. The adult designated by the patient is called the Patient Advocate.

1. If the patient has executed a DPOA and is subsequently found to be incompetent, the consent of the Patient Advocate is necessary for non-emergent medical/surgical treatment or psychiatric treatment and for emergency treatment if readily available.
   a. For medical/surgical treatment, incapacity is determined and documented by two physicians or by one physician and a licensed psychologist.
   b. For psychiatric treatment, incapacity is determined and documented by two physicians, one of whom is a licensed psychiatrist.

2. Before the Patient Advocate may make treatment decisions for the patient, the Patient Advocate must sign an Acceptance Form. Both the DPOA and the Patient Advocate’s Acceptance Form must be part of the patient’s medical record.

**iii. Family**

1. If it is determined that the patient is incompetent and the patient does not have a legal guardian or a Patient Advocate acting under a DPOA, then the next of kin may consent to medical/surgical treatment provided all of the following conditions are met:
   a. The treating physician, relying on his/her medical judgment, believes the treatment, though not emergent, should not be delayed until the patient recovers sufficiently to give consent; and
   b. The treating physician documents these reasons in the patient’s medical record; and
   c. Neither the physician nor the next of kin knows, or has reason to know, that the patient, if competent, would be opposed to the proposed medical/surgical treatment, given the specific set of circumstances.

2. Consent should be obtained from the closest next of kin in the following order of priority:
   a. Spouse
   b. Adult son or daughter
   c. Either parent
   d. Adult sibling

3. When the person with the highest priority is not available, the next in order should be contacted. It is strongly recommended that the consent of persons, other than those listed above, be used with caution. The more distant the relationship between the patient and the next of kin, the greater the probability that the procedure should be delayed until consent can be obtained from a person authorized to give consent, such as a Legal Guardian.

4. The opinion of a patient’s domestic partner, including those of the same sex as the patient, should be considered for purposes of consent. If conflict arises between a
domestic partner and the next of kin, then an Ethics consultation should be obtained and Legal Affairs should be contacted.

5. If the patient’s lack of competency is long-term or unrelated to the present illness, appointment of a Legal Guardian should be discussed with the family.

c. If the patient is not competent and there is no surrogate decision maker, the treating physician should contact the Department of Legal Affairs to request appointment of a Legal Guardian.

d. If a question arises regarding consent on behalf of an incompetent patient or there is disagreement among next of kin or between the treating physician and surrogate decision maker, the treating physician should contact the Department of Legal Affairs.

3. **Medicated Patients.** A patient should never be informed of the proposed treatment, alternatives, risks, benefits, complications, prognosis, and goals if he/she is mentally impaired by virtue of medication or abused substances. If a patient has been given an anesthetic agent, the patient is incapable of giving consent until 24 hours after administration of the anesthetic agent.

   a. If the physician will attest in the medical record that the patient received sufficient information and did consent to the treatment prior to receiving the medication, the proposed treatment may proceed without a Form #232 being signed.

   b. If the physician cannot document that sufficient information was given prior to the administration of the medication, the treatment will be delayed until the patient is capable of understanding and consenting.

   c. Sterilization/therapeutic abortion may not proceed unless a Form #232 is signed prior to pre-operative medication.

4. **Minors.** Except in emergency cases, the consent of a parent, Legal Guardian, or person acting in place of the parents is required in providing medical or surgical treatment to an individual under age eighteen (18). The assent of the minor, as appropriate for age, should be sought in conjunction with obtaining parental consent and the minor’s assent, or lack thereof, should be documented in the medical record. If the minor does not assent, Clinical Ethics consultation should be considered.

   a. **Minor Living at Home but Parent Unavailable:** If a minor requires medical and/or surgical care and the parents are temporarily unavailable, the physician should obtain consent from the minor’s nearest available adult relative or person with a written delegation of parental rights acting in place of the parents. The medical record should reflect the fact that attempts were made to contact the minor’s parents. In addition to providing discharge instructions to the responsible adult, a copy of relevant discharge instructions should be mailed to the minor’s parents at their home address.

   b. **Minor’s Parents are Divorced or Legally Separated:** If the parents are legally separated or divorced, the court will have awarded custody. If parents have joint legal custody, then either parent may consent. If one parent has been awarded legal custody of the minor, then that parent’s consent should be obtained. In the event of a dispute, the parents should be required to produce a written Judgment of Divorce and the Department of Legal Affairs must be contacted immediately.

   c. **Parental Refusal of Treatment:** If, in the opinion of the attending physician, a minor requires medical treatment and the parents refuse to consent, a court order may be obtained under the Child Abuse and Neglect Act. Contact the Department of Legal Affairs immediately.

   d. **Minor Not Living at Home and Without Legal Guardian:** If a minor is not living with his/her parents and does not have a Legal Guardian, consent to routine non-surgical medical care may be
obtained from the Circuit Court – Family Division or the Michigan Department of Human Services. If a question arises in this circumstance, the Department of Legal Affairs should be contacted.

c. Minor Lives in Foster Home or Residential Care Facility
   i. Consent for minors in foster care depends upon the nature of the proposed treatment and the type of placement as follows:

<table>
<thead>
<tr>
<th>Type of Care</th>
<th>Type of Placement</th>
<th>Who May Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine, non-surgical care (other than contraceptive treatment, services, or devices)</td>
<td>Involuntary placement by Court</td>
<td>Court, child placing agency, Michigan Department of Human Services, or the residential care provider to which they have delegated such authority in writing</td>
</tr>
<tr>
<td>Routine, non-surgical care (other than contraceptive treatment, services, or devices)</td>
<td>Voluntary placement by parent/Legal Guardian</td>
<td>Parent/Legal Guardian</td>
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<tr>
<td>Emergency medical or surgical care</td>
<td>Involuntary placement by Court</td>
<td>Court, child placing agency, Department of Human Services, or the residential care provider to which they have delegated such authority in writing</td>
</tr>
<tr>
<td>Emergency medical or surgical care</td>
<td>Voluntary placement by parent/Legal Guardian</td>
<td>Residential care provider to which parent must delegate such authority in writing</td>
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<tr>
<td>Non-emergent, elective surgery</td>
<td>Voluntary or Involuntary placement</td>
<td>Parent/Legal Guardian OR</td>
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<td>If parental rights have been permanently terminated, then the Court or Department of Human Services</td>
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ii. Although the consent of the parent or Legal Guardian is typically required for minors prior to commencing treatment, Michigan law permits a minor in some instances to consent to medical or surgical treatment on his/her own behalf.

f. Emancipated Minors: Emancipation means a parent is no longer legally responsible for a minor. It occurs in the following instances:
   i. Where a minor is legally married.
   ii. During the period when a minor is on active duty with the Armed Forces of the United States.
   iii. For the purpose of consenting to routine, non-surgical medical care or emergency care, when the minor is in the custody of a law enforcement agency and the minor's parent or Legal Guardian cannot be promptly located.
   iv. Upon entry of an emancipation order by the Circuit Court – Family Division

g. Substance Abuse, Venereal Disease or HIV: Minors may consent to medical advice or treatment for substance abuse, venereal disease or HIV (AIDS, ARC) without parental consent.
i. **Substance Abuse:** The minor must consent for a treating physician to inform the parents of treatment.

ii. **Venereal Disease or HIV:** A treating physician may inform the parents of treatment, even if the minor specifically requests that the physician not inform his/her parents of the treatment.

h. **Birth Control Information and Devices:** Minors may obtain birth control information, medication and devices without parental consent.

i. **Mental Health Services:** Minors over the age of 14 may seek and receive outpatient mental health services, excluding pregnancy termination referral services and the use of psychotropic drugs, without parental consent for up to twelve (12) sessions or four (4) months.

j. ** Abortions:** A minor may not obtain an abortion without the written consent of one (1) parent or the minor’s Legal Guardian, unless the Circuit Court – Family Division has entered a written order waiving the parental consent requirement. A parent’s written consent or the Court’s order waiving parental consent must be included in the medical record together with the written consent of the minor.

k. **Prenatal and Pregnancy Related Health Care:** A minor female may seek and consent to prenatal and pregnancy related health care and to the provision of health care for her child without the consent of her parents.

   i. Prenatal and pregnancy related “health care” is defined by law as “only treatment or services intended to maintain the life and improve the health of both the minor and the minor’s child or fetus.” Prior to treatment, the Hospital or physician is required to inform the minor that while the physician is not obliged to notify the spouse, parent, Legal Guardian, or putative father of the child, the law does not prevent such notification.

   ii. The physician, for medical reasons, may inform the spouse, parent, Legal Guardian, or putative father of the child regardless of the minor’s consent or lack thereof.

   iii. The medical record should reflect the fact that the minor has been informed that notification of others regarding her treatment may occur.

l. **Blood Donation:** A person 17 years of age or over may donate blood in a voluntary and non-compensatory blood program without the necessity of obtaining the permission or authorization of a parent or Legal Guardian.

m. **Sterilization:** The law is silent as to whether a married minor may consent to be sterilized without spousal or parental consent. The Department of Legal Affairs should be contacted in all cases involving sterilization of minors. For the patients who are Medicaid recipients, federal regulations prohibit funding for any person under age 21.

**GOVERNING POLICY**

This policy is to be considered the governing policy of Beaumont Health System. All previous policies not in conformance with this policy are no longer valid.
POLICY:
Patients have the right to refuse care, treatment, or other services in accordance with law and regulation. When patients are not able to make decisions for themselves; a surrogate decision maker may refuse care, treatment, and other services in accordance with law and regulations.

For further information see Patient Care – Corporate Policy: Patient Rights and Responsibilities.

GENERAL
A competent, adult patient who knowingly and contemporaneously refuses the transfusion of blood or blood products may be admitted and treated at William Beaumont Hospital. The patient must sign Form #7488, "Refusal of Blood Transfusion and Release" (available through Forms Library) if refusing blood. Grosse Pointe uses form # 610-49 "Refusal to permit treatment / procedure/ medication". Questions concerning competent, adult patients whose beliefs prohibit the transfusion of blood or blood products should be handled according to this policy.

ALL CASES involving minor patients, incompetent patients, whether minor or adult, and pregnant females, whether minor or adult, where transfusion of blood or blood products is declined, must be referred to the Department of Legal Affairs.

Definitions:

Competent Adult: A competent adult is one who is eighteen (18) years of age or older and can understand his/her medical condition and proposed treatment, risk and benefits of proposed course of treatment and non-treatment, prospects for treatment, and significant alternative treatment.

Incompetent Adult: An incompetent adult is one who cannot understand his/her medical condition, proposed treatment and alternative treatments.
POLICY

This policy presents guidelines for complete, accurate, and timely reporting of circumstances involved in any occurrence in any of the divisions of Beaumont Health System.

PURPOSE/INTENT

The Institute of Medicine defines quality as: “the extent to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.” Continuous improvement of patient safety is our guiding principle in achieving quality and reducing morbidity and mortality.

Occurrences shall be reported, analyzed,的趋势, and utilized through review processes to continually improve systems, processes, education and training to reduce/avoid their occurrence. Systems shall be designed for safety, and system failures shall be corrected to reduce the risk associated with human error. Systems shall strive to minimize both the frequency and impact of occurrences.

All employees and practitioners are responsible for fully cooperating in efforts to improve patient safety, reduce risks and minimize occurrences. This includes the reporting of occurrences that result in actual or potential injury to a patient.

Patients and their families will be informed about injuries resulting from occurrences. (See policy #319, Disclosure of Unanticipated Outcomes).

DEFINITIONS

**Occurrence:**

An occurrence is any process/incident inconsistent with the routine operation of the hospital or the routine care of patients in any setting. This includes errors that result in actual or potential injury to a patient or visitor, including near misses or unsafe conditions.

**Sentinel Event:**

A Sentinel Event is any unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. The phrase, “or risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. An “unexpected occurrence” is one that results in an unanticipated death or major permanent loss of function, not related to the natural course of the patient’s illness or underlying condition.

Refer to Sentinel Event Policy #219
DEFINITIONS
(Cont’d)

High Priority Reviews:
A High Priority Review is a complete, thorough, in-depth analysis which focuses primarily on processes and systems to discover causal factors leading up to an occurrence and to develop and implement risk reduction action plans to prevent recurrences.

Process Owner:
A designated individual responsible for each occurrence category. Process Owners are responsible for follow up, referring for Organization or Department Review, performance improvement recommendations, referring for further department or organization review, tracking and trending.

CONFIDENTIALITY

Any records, data, and information collected for or by individuals involved with an occurrence and the subsequent review and analysis are part of a professional, peer review function, performance improvement effort or other quality initiative and are confidential and protected from discovery and subpoena pursuant to MCLA 333.20175, 333.21513, 333.21515, 331.531-533. Copies of Patient Safety and Quality Improvement Reports must not be given to patients/visitors or placed in the medical record.

INQUIRIES

All inquiries concerning Patient Safety and Quality Improvement Reports should be directed to:
- Quality and Patient Safety (Royal Oak)
- Quality and Patient Safety (Troy)
- Quality and Patient Safety (Grosse Pointe)
- Quality and Patient Safety (Home Health Services)

DETAILED PROCEDURES

218.1 Preparation & Processing of Patient Safety and Quality Improvement Reports.
218.2 Preparation and Processing of Patient Safety and Quality Improvement Reports Affected by Safe Medical Devices Act.
319 Disclosure of Unanticipated Outcomes.
POLICY:
A Patient Safety & Quality Improvement (PSQI) is required for any incident or occurrence that is inconsistent with the routine operation of the hospital or the routine care of patients (see policy #218).

GENERAL INFORMATION

1. PSQIs are to be utilized to identify opportunity for process improvement. Staff are encouraged to complete a Patient Safety and Quality Improvement report in the event of a near miss or unsafe condition in addition to an actual event.

2. Examples of incidents NOT requiring a PSQI report include:
   - Patients leaving the hospital against medical advice (unless the patient is at substantial risk of harm) – document AMA in the medical record.
   - Property loss or theft of employee belongings – notify Security.
   - Lost patient items – notify Lost & Found.
   - Employee injury – report of form #553 – Employee Accident and Illness. Also on the PSQI site, electronically.

RESPONSIBILITY

1. Person who first discovers an occurrence should:
   - Notify the appropriate department manager or supervisor.
   - Initiate an electronic PSQI report. This report may be initiated by any Beaumont employee or physician. (See specific directions for completing the electronic report.)
   - If the occurrence involves a medical device, remove the medical device from service/sequester the piece of equipment for further investigation, retrieve any historic data from the equipment if possible, record the WBH tag number on the appropriate repair document. Send the item to Clinical Engineering Department as appropriate.
   - Coordinate communication to patient/family according to the Guidelines outlined in policy #319, Disclosure of Unanticipated Outcomes.
RESPONSIBILITY (Cont’d)

2. Department Manager/Supervisor:
   - Consider whether Sentinel Event or High Priority Review consideration is appropriate. If yes, refer to Patient Care, Corporate policy #219 – Sentinel Events for definitions, criteria, and notification instructions.
   - Review the PSQI report for completeness and accuracy.
   - Complete the Manager Review section on the electronic PSQI report (See specific directions for completing the electronic report.) Evaluate the following factors in this review:
     - Impact on patient care/outcome.
     - Actions taken regarding correction and prevention.
     - Document additional findings and follow up actions.
     - Document condition of patient if an injury has occurred.

3. Process Owner:
   - When a PSQI report is initiated the process owner will receive an email notice that the report has been completed. At this point the process owner must review the report in the QASYSTEMS database and determine the manager that needs to complete the Manager Review section.
   - Send an email notification to the appropriate manager to complete the electronic review.
   - When the Managers Review is complete, another email message will be sent to the process owner. Process owner must enter the QASYSTEMS database to determine if other information is needed and to begin any necessary follow-up.
   - Analyze, track and trend, and make process improvement recommendations on an on-going basis. Provide appropriate reports to the Quality and Patient Safety Department for each respective division for any completed process improvements resulting from the PSQI process.

ELECTRONIC PSQI DIRECTIONS

1. PSQI Initiation: (this information is also available on Inside Beaumont)
   - Open the Inside Beaumont web page.
   - In the web tool bar, place your cursor over the word “Quality”.
   - Select “PSQI Report” from the dropdown list. The Patient Safety page will open.
   - On the left hand side of the Patient Safety page, select “Patient Safety and Quality Improvement Report”. You will be linked to the web report.
   - Place your cursor over the Patient Safety and Quality Report. (It will show up in the box below.)
ELECTRONIC PSQI DIRECTIONS (Cont’d)

- Click on the “select” button and the PSQI form will appear on the screen.
- The PSQI system will time out after 20 minutes of inactivity. Do not leave the computer once you have started entering a PSQI report.
- Provide as much information as you can, using dropdown menus whenever available. Include as much pertinent information as possible in the appropriate fields. In the general description box includes all pertinent information such as medication names, dosages, and routes of administration, equipment identification numbers and disposition, contributing factors, etc. All yellow highlighted fields require information to be entered.
- Once all available information has been entered, click on the “Next” button.
- If this PSQI report requires an addendum, the addendum will be the next screen to appear. Answer all the questions that apply. If the PSQI does not require an addendum, the next screen will direct you to review the previous information, submit the form, or cancel.
- If the information is complete, select the submit button and a summary screen will appear. (At this point, if you need a printed copy of the report, use the Windows tool bar select print and the report will be sent to your designated printer. This will be a screen print, not the entire document.)
- At the bottom of the screen is a button labeled “Finish”. This is the log out button that will take you back to the first screen. The report has already been submitted.

2. Department Manager Review: (this information is also available on Inside Beaumont)
   - Open the Inside Beaumont web page
   - In the web tool bar, place your cursor over the word “Quality”.
   - Select “PSQI (Review Manager)” from the dropdown list and the Patient Safety page will open.
   - On the left hand side of the Patient Safety page, select “Department Manager Review”.
   - Click on the “select” button and the form will appear on the screen revealing everything that was entered when the report was initiated and the boxes to be completed by the department management representative.
   - The Reviewer Name and Notes sections are to be completed. Enter any information pertinent to your follow up, for example, condition of patient, actions taken immediately to prevent recurrence, or other investigation findings.
   - Once all available information has been entered, click on the “Next” button at the bottom of the page.
   - On the next screen review the information for accuracy and completeness. If the information is complete, select the submit button and a summary screen will appear. At this point, if you need a printed copy of the report, use the Windows tool bar select print and the report will be sent to your designated printer.
2. **Department Manager Review**: (Cont’d)
   - At the bottom of the screen is a button labeled “Finish”. This is the log out button that will take you back to the first screen. The report has already been submitted.

**GENERAL DOWNTIME INSTRUCTIONS**

A copy of the Downtime instructions for completion of Patient Safety and Quality Improvement Report (PQSI) is available on the Patient Safety Page or the Documents page of the Inside Beaumont and in the forms library. If the server is down and you must use a paper PSQI report, please make a copy of the completed front page to be sent to the quality department within 24 hours. The original should be given to the department manager for completion of the department review.

1. **Person initiating the PSQI report**: Obtain the paper copy. Complete the form according to the following directions.

2. **Patient Identification**: Each PSQI report generated must have patient identification information, which includes patient name, medical record number, facility where the patient is receiving treatment and the room number or unit where the event occurred.

3. **Date and Time** - date of event, military time

4. **Type of patient** - inpatient, outpatient, visitor, other (i.e., vendors, employees involved in events that also affect patients. *Employee injuries generally should be reported on an Employee Illness/Accident Form – form #553.

5. **Category** – check the ONE that best describes the occurrence.

6. **Equipment or Medical device** – remove the equipment from service, record the WBH tag number, and immediately call or send the item to Clinical Engineering with a copy of the PSQI Report, see policy 218.2.

7. **Injury** – indicate the type of injury sustained. This information is based on the information available at the time the report is being written.

8. **Severity** – indicate the appropriate level of injury. “Error discovered before patient contact” is intended to report near misses or errors that could have resulted in harm to the patient.

9. **Description** – provide as much information as possible to describe what happened, and any actions taken to stabilize the patient or situation.

10. **Medical Consequences**: If the person involved sustained an apparent or probable injury provide as much information as possible.
GENERAL DOWNTIME INSTRUCTIONS (Cont’d)

11. Make a copy of the completed form and send the copy to the department listed below:

   Royal Oak Hospital – Quality and Patient Safety, 112 ABW - RO
   Troy Hospital – Quality and Patient Safety, 200 – Troy
   Grosse Pointe Hospital – Quality and Patient Safety, 700 - GP
   Grosse Pointe Hospital – Legal Affairs, 700 – GP
   Home Services – Quality and Patient Safety, 1410 HSC

   Give the original report to the Department Manager responsible for the area or treatment involved in the incident. This report must be sent to the appropriate Quality and Patient Safety Department as soon as possible.

12. Department Review: This section is to be used by the department management personnel for comments describing their assessment of the situation and any actions taken to avoid recurrence. Include disclosure information if there is an injury involved. Once complete, send the form to the appropriate process owner, based on the category chosen.

13. Process Owner Follow-up: This section of the form is dedicated to the process owner who is responsible to enter the information in to the QASYSTEMS database for analysis, trending, and other process improvement actions.

14. Process Owner: If you receive a paper copy of the PSQI report that contains a number at the top, follow your normal processes for entering the data into QASYSTEMS and other follow up as needed. If you receive a copy that does not contain a number, contact your division’s quality and safety department for further direction.

15. Quality Departments:
   • Receive and file paper copies of PSQI reports until they can be entered into the database by the appropriate process owner when the service is functioning again. Once entered into QASYSTEMS the paper copies may be shredded.
POLICY

To provide an efficient and effective process for investigating incidents associated with medical devices, equipment, single-use medical devices, and disposable medical products. The process aims to find the root cause of an incident and to subsequently define measures for preventing similar incidents and improving systems. This is to be done in a constructive, non-punitive manner, consistent with Beaumont Health System Corporate Human Resource Policy #215.

GENERAL

1. The department of Clinical Engineering and Technology Management (CE&TM) leads incident investigations when any medical device, medical equipment, a single-use medical device (SUD), and/or a medical disposable product are involved.

2. Each PSQI incident is determined to be FDA SMDA reportable, or not reportable, and pertinent information is logged into the PSQI database (QASYS). The Clinical Engineer (CE) collects information from a variety of sources during the investigation to identify the root cause(s) of the incident. The CE, along with the involved hospital department(s), evaluates measures to correct the problem or minimize recurrence and publishes these in the monthly Equipment Quality & Planning Committee (EQPC) Report.

3. Where the root cause(s) can not be determined, i.e., where the data collected is insufficient or inconclusive, the CE will provide the client(s) reasonable recommendations to mitigate or correct the problem and avoid a recurrence. CE will maintain all data collected in QASystems (the central PSQI database) and monitor PSQI incidents for emerging trends to address.

DEFINITIONS

1. Department Review: This is the department where the PSQI incident took place and which generated the PSQI incident report. The department is not necessarily the process owner when the incident involves medical equipment.

2. Incident: Any process, occurrence, or outcome inconsistent with the routine operation of the hospital or the routine care of patients.
DEFINITIONS (Cont.)

3. PSQI Event/Incident: Any process, occurrence, or outcome inconsistent with the routine operation of the hospital or the routine care of patients AND where process and/or technology improvement is deemed to be an effective remedy to minimize risk of recurrence. This includes errors that result in actual or potential injury to patients, visitors, or clinicians.

4. PSQI Investigation Report: This presents and summarizes the outcomes and recommendations of CE&TM’s investigation of any medical equipment-related PSQI incident.

INVESTIGATION

1. As much as possible, obtain firsthand information about the PSQI incident and the involved medical devices and disposables. If necessary, contact the department head where the incident took place for permission to interview witnesses.

2. Determine if the PSQI event/incident is SMDA reportable, either mandatory or voluntary, or not reportable. If an event/incident is deemed reportable to the FDA under the guidelines set forth by CE&TM and the Safe Medical Devices Act of 1990, follow procedures outlined by the CE & TM SMDA SOP. Report mandatory or voluntary reportable incidents to MedSun following the CE&TM SMDA & MedSun SOP.

REPORTING

1. Notify department manager or assistant manager and person who wrote up the PSQI of CE&TM’s receipt of the PSQI and any preliminary actions taken.

2. Once all the relevant information has been reviewed, determine the proper corrective action and if necessary, write a Confidential Peer Review PSQI investigation report to the appropriate representative of the reporting department. Where a written report is unnecessary, notify the department of actions taken and CE&TM’s recommendations.

ADDITIONAL REFERENCES

JLL Policy: SOP- Patient Safety and Quality Improvement (PSQI) Reporting, where CE & TM are the process owner.
POLICY STATEMENT:

To improve patient care through a timely and systematic review and response to significant patient safety events in accordance with the quality improvement functions of the corporation.

DEFINITIONS:

A Sentinel Event or Significant Patient Safety Event is any unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injuries specifically include a loss of limb or function. The phrase, “or risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. An “unexpected occurrence” is one that results in an unanticipated death or major permanent loss of function, not related to the natural course of the patient’s illness or underlying condition. Occasionally, an event is the type of incident that is extremely severe and/or could draw media attention and should be considered a Potential High Profile event.

Any occurrence that meets the above definition or any of the following criteria must be referred for Sentinel Event consideration:

- Any patient death, paralysis, coma or other major permanent loss of function associated with a medication error.
- Suicide of any patient receiving care, treatment and services in a staffed around-the-clock care setting or within 72 hours of discharge.
- Any elopement, that is unauthorized departure, of a patient from an around-the-clock care setting resulting in a temporally related death (suicide, accidental death, or homicide) or major permanent loss of function.
- Abduction of any patient receiving care, treatment, and services
- Death of a full-term infant (unrelated to a congenital condition in an infant having a birth weight greater than 2500 grams).
- Any intrapartum (related to the birth process) maternal death.
- Discharge of an infant to the wrong family.
- Surgery on the wrong patient or wrong body part.
- Assault, homicide, or other crime resulting in patient death or major permanent loss of function.
- Rape
- A patient fall that results in death or major permanent loss of function as a direct result of the injuries sustained in the fall.
- Unintended retention of a foreign object in a patient after surgery or other procedure.
- Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter).
- Prolonged fluoroscopy with cumulative dose >1500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose.
- Any others that may be deemed reviewable by the Joint Commission.
Any Beaumont employee who discovers an event that could possibly meet these conditions should immediately follow the steps outlined in this policy.

GENERAL GUIDELINES:

1. Persons closest to the potential sentinel/significant patient safety event (immediately)
   - Stabilize the clinical situation.
   - Notify immediate supervisor.
   - Reduce immediate risks of recurrence.
   - Document clinical information in the medical record.
   - Document the occurrence of the event on a Patient Safety and Quality Improvement Report Form according to policy 218 and 218.1.
   - If the Significant Patient Safety Event involves a medical device or piece of equipment, remove and preserve the device or piece of equipment and all associated components and immediately notify Biomedical Engineering.

2. Supervisor’s actions (within the first 24 hours)
   - Review immediate actions.
   - Immediately notify the divisional Quality and patient Safety Director via alpha page (all hours)
     - Royal Oak pager 248-995-4049 (office 248-551-0279)
     - Troy pager 248-995-0265 (office 248-964-5905)
     - Grosse Pointe pager 248-995-7527 (office 313-473-1415)
     * The Quality Department will make further notifications as necessary according to established protocols.
   - Coordinate communication to patient/family according to the Guidelines outlined in policy #319, Disclosure of Unanticipated Outcomes.

Root Cause Analysis

A root cause analysis is a process for identifying the basic reason(s) or causal factor(s) for the occurrence which, if eliminated or corrected, would have prevented the Sentinel Event from occurring.

Sentinel Event Notification processes

All divisions will be made aware when a sentinel event has occurred. Once this notice has been received, a general message will be sent to the predetermined notification list for administration and medical leadership.
GUIDELINES

A Root Cause Analysis will be completed on all Sentinel Events. A task force will be formed to complete this analysis. Individuals performing the Root Cause Analysis will include the organization’s leadership and appropriate individuals involved in the processes and systems under review.

Disclosure of Unanticipated Outcomes: If the Sentinel Event has resulted in an Unanticipated Outcome, the Patient/family shall be made aware pursuant to the guidelines presented in policy #319, Disclosure of Unanticipated Outcomes.

CONFIDENTIALITY

Any records, data, and information collected for or by individuals involved with a Sentinel Event and the subsequent review and analysis are part of a professional, peer review function, performance improvement effort or other quality initiative and are confidential and protected from discovery and subpoena pursuant to MCLA 333.20175, 333.21513, 333.21515, 331.531-533.

INQUIRIES

All inquiries concerning Sentinel Events should be directed to the hospital Quality and Patient Safety departments.

DETAILED PROCEDURES:

Patient Safety and Quality Improvement Report, 218
Disclosure of Unanticipated Outcomes, #319.
PURPOSE

Patients have the right to receive accurate, timely and easily understood information regarding all clinical events so that they can make informed decisions about their care. Patients and, when appropriate, their families are entitled to information about the outcomes of diagnostic tests, medical treatment and surgical intervention whether the results are expected or unanticipated. When an Unanticipated Outcome occurs, the patient is entitled to a timely explanation of the Unanticipated Outcome and its short and long-term effects. When an error contributed to the Unanticipated Outcome, the patient must be provided an honest and compassionate explanation of the error and the medical treatment available to the patient. The patient should also be informed that the factors involved in the Unanticipated Outcome will be reviewed so that corrective measures can be taken to reduce the possibility of similar outcomes in future patients.

DEFINITIONS

An Unanticipated Outcome is a result that differs significantly from what was anticipated to be the result of a diagnostic test, medical treatment, or surgical procedure. An Unanticipated Outcome includes a Sentinel Event or an Occurrence, as defined in Patient Care Corporate Policy #218 (Patient Safety and Quality Improvement Report), which results in actual injury or places the patient at risk for injury, for which monitoring and/or follow-up will be required. An Unanticipated Outcome may or may not be associated with an error. Errors discovered during retrospective peer review and/or quality assurance process are not subject to this policy. Contact the appropriate medical staff Chief of Service if there are any questions regarding application of this policy.

GUIDELINES FOR RESPONDING TO AN UNANTICIPATED OUTCOME

The order in which the following guidelines are implemented may vary depending on the individual situation. In every instance of an Unanticipated Outcome, however, caring for the patient’s immediate needs should always come first. The Medical Chief of Service and Director of Nursing, in collaboration with the attending physician, nurse manager and/or department manager are responsible for implementing the following guidelines. If necessary, reference Patient Care - Corporate Policy #312, Chain of Command, to assure compliance with this policy.

1) **Care for the Patient:** Address the current health care needs of the patient. The patient’s attending physician should be immediately notified of the Unanticipated Outcome and all necessary tests and/or consults ordered.
GUIDELINES FOR RESPONDING TO AN UNANTICIPATED OUTCOME (Cont’d)

2) **Preserve the Evidence:** If the Unanticipated Outcome involves a medical device (pump, anesthesia machine, etc) or medical equipment (syringes, IV tubing, medication vials or packaging, etc), remove the device/equipment from service and immediately contact Biomedical Engineering at x16300 (RO & GP), x41070 (Troy). The medical device or equipment and related packaging materials should be preserved and turned over to Biomedical Engineering.

3) **Document in the Medical Record:** At the time of the Unanticipated Outcome, *objectively* document the facts known about the Unanticipated Outcome in the patient’s medical record. Include the medical care provided in response and the plan of treatment.

4) **Complete a Patient Safety and Quality Improvement Report:** If the Unanticipated Outcome meets the definition of an Occurrence or Sentinel Event, an electronic patient safety and quality improvement (PSQI) report should be completed pursuant to Patient Care Corporate Policy #218. Contact the Quality & Patient Safety Department at Royal Oak, Troy or Grosse Pointe as appropriate immediately if the Unanticipated Outcome requires Sentinel Event or High Priority Review consideration.

5) **Initial Disclosure:**
   - An Unanticipated Outcome should be communicated to the patient, or appropriate guardian or representative, if there are clinical consequences or, if a reasonable person would want to know, regardless of whether any negative clinical consequences resulted.
   - The Medical Chief of Service and Director of Nursing are responsible to assure that the process of disclosure occurs in a timely and appropriate manner.
   - In rare instances, where it can clearly be demonstrated that the interests of the patient are harmed by disclosure, discussion of an Unanticipated Outcome may be withheld until the benefits of disclosure are greater than the harms. The reasons for this exception should be documented in the Patient Safety and Quality Improvement Report.
   - The initial disclosure should take place in a timely manner after the Unanticipated Outcome is identified and the immediate health care needs of the patient have been addressed.
   - The discussion of Unanticipated Outcomes is the responsibility of the patient’s attending physician of record. A team approach may be necessary, however, as determined by the attending physician, nurse manager and, as necessary, the department manager. It is recommended at least one other individual from the hospital or medical staff be present to witness the discussion. The patient should be given the option of having another person with them as support during the discussion.
   - A nurse may discuss minor occurrences that do not result in morbidity, such as a patient fall without injury.
GUIDELINES FOR RESPONDING TO AN UNANTICIPATED OUTCOME (Cont’d)

5) Initial Disclosure: (Cont’d)

➢ A meeting may be called with the attending physician and the disclosure team to discuss the presently known facts prior to the discussion with the patient and/or family. If the attending physician considers it appropriate, Legal Affairs, Corporate Communications and/or the Director of the Ethics Consult Service may be requested to assist in preparation for this meeting.

➢ The attending physician or, when appropriate, a designee and/or the disclosure team should discuss the situation with the patient and/or family. If necessary, consult pastoral care or social work to assist in the disclosure.

➢ The discussion should include:
  ▪ An understandable, objective, factual explanation of the Unanticipated Outcome;
  ▪ The follow-up treatment/monitoring plan for the patient;
  ▪ Assurances that the Unanticipated Outcome is being investigated and information will be shared with the patient and/or family when this investigation is complete;
  ▪ Immediate measures taken to prevent recurrence;
  ▪ An opportunity for the patient/family to express his/her perception of the significance of the event.
  ▪ An apology that an Unanticipated Outcome occurred. NOTE: while expressions of sympathy, condolence and understanding may be appropriate, an admission of fault or responsibility should not be made until completion of the event review or Root Cause Analysis.
  ▪ The name and phone number of an individual in the hospital to whom the patient may address complaints or concerns about the Unanticipated Outcome.

➢ Verify the patient’s/family’s understanding of the unanticipated outcome and answer questions they might have.

➢ Make an appointment for follow-up phone call or visit with patient and/or family and encourage patient and/or family to call if they have questions. Provide patient and/or family with the name and number of a contact person.

➢ The discussion of the Unanticipated Outcome with the patient/family must be documented in the medical record. This documentation should include the time, date and place of the discussion, the names and relationships of those present, a summary of the information provided and questions answered, an offer of assistance and the response to it.
GUIDELINES FOR RESPONDING TO AN UNANTICIPATED OUTCOME (Cont’d)

6) Analyze Unanticipated Outcome:
   ➢ All Unanticipated Outcomes involving errors should be analyzed to prevent recurrence and improve future patient care. All Unanticipated Outcomes should be reported in a Patient Safety and Quality Improvement Report. Notification to the appropriate Quality and Patient Safety Department must be made for further assessment and, depending on severity, Sentinel Event or High Priority review (refer to Patient Safety and Quality Improvement Report Policy #218 and Sentinel Event Policy #219). This analysis is performed pursuant to Michigan’s peer review statutes and is confidential and protected from discovery and subpoena pursuant to MCLA 333.20175, 333.21513, 333.21515 and 331.531-533.

7) Follow Up Disclosure:
   ➢ This is when the attending physician and/or disclosure team should discuss the details of “how” and “why” the Unanticipated Outcome occurred.
   ➢ The designated contact person should call back the patient and/or family as promised or as needed. Offer to meet with patient and/or family to discuss non-confidential information and findings regarding the analysis of the Unanticipated Outcome.
   ➢ Providing an explanation of what occurred should not involve expressions of blame. However, if indicated by the investigative findings, an organizational apology and corporate admission of fault may be offered. The Chief of Service should determine the appropriateness of an admission of fault after his/her review of the investigative findings. The Director of the Ethics Consult Service and/or Department of Legal Affairs may also be asked to provide a review of the findings and to make a recommendation in this regard.
   ➢ If the patient is still in the Hospital, document the discussion in the medical record. If the patient is discharged, document the discussion as determined appropriate by Legal Affairs.

8) Employee Assistance Referral: Acknowledge the effect an Unanticipated Outcome may have on members of the health care team and refer them to the Employee Assistance Program when necessary. Refer to Human Resource Manual Policy #269: Employees Involved in Clinical Errors.

RELATED POLICIES

- Patient Safety and Quality Improvement Report Policy, 218
- Sentinel Events Policy, 219.
- Chain of Command Policy, 312.
- Employees Involved in Clinical Errors Policy, 269 (Corporate Human Resources Manual).
- Patient Information Confidentiality Policy, 314.

PATIENT CARE – CORPORATE POLICIES

Disclaimer: User must ensure that any printed copies of this policy/procedure are current by checking the policy/procedure web page before use.
Documentation Guidelines
Risk Management
Principles & Commentaries
for the Medical Office

2nd Edition
SECTION 1

Documentation and Patient Medical Records

1.01 Periodic review of patient office records should be conducted using the following criteria:

(a) Accuracy - Clinical facts, findings, test results, and the like, should be consistent and complete. Dictated notes and reports should be dated and proofread to ensure accuracy and completeness.

(b) Objectivity - Subjective or personal remarks or notations about the patient should be clearly supported by documented facts; the patient’s impressions or comments should be clearly identified as such by quotation marks; clinical findings and diagnoses should be supported in context by objective data or earlier noted observations in the record; subjective comments about the care of other providers should never be noted in the patient record.

(c) Legibility - The record should be legible; use of abbreviations should be appropriate and unambiguous; changes in the record should be consistent with appropriate hospital medical records documentation standards and prior entries not rendered unreadable.

(d) Timeliness - Entries following patient office encounters should be timely. It is suggested that records be prepared as contemporaneously with treatment as possible, and, if appropriate, dictated in the presence of the patient. Similarly, documentation of laboratory and other reports should reflect that they are received, reviewed by the treating/attending physician, and filed in the patient record in a timely fashion.

(e) Comprehensiveness - Conclusions should be charted with documentation of rationale or intermediate clinical steps; critical decision points should include documentation of the physician’s clinical assessment or reason(s) for making the decision; patient management activities should be appropriately documented, including the coordination of care among providers and follow-up activities.

(f) Alterations - Inappropriate alterations include missing pages, erasures or obliterations, removal of sections of the record, or missing items such as lab test reports, radiology films, and EKG strips. It is recommended that all
chart contents be fastened securely to the jacket. Any additions or corrections to the record must be dated and signed, and the date must reflect the day the addition or correction is made.

NOTE: The procedure for reviewing patient office records should be designed and carried out in a manner that maintains the strict confidentiality of patient records. Appropriate legal and/or risk management consultation should be obtained when necessary.

1.02 Physicians should keep original medical records in their possession.

Commentary:
Although the information contained in the medical record belongs to the patient, the physical record itself belongs to the physician. Physicians should provide a copy or summary of the record but always maintain the original in their possession. Physicians should be aware of state laws addressing retention of and access to medical records and physician office records.

1.03 Physicians should provide patients with access to their medical records subject to provisions of state law. If the law is silent as to such access, patients should be provided with at least a written summary of the office record, but only upon written request signed by the patient.

1.04 A copy or summary of a patient's office record should be released pursuant to an attorney's request only after:

(a) The patient's physician has reviewed the record and request;

(b) The request has been accompanied by a written authorization dated and signed by the patient, or made pursuant to a court order or other legally enforceable court mandate (physicians are encouraged to first consult their attorney when presented with a court order to produce patient records);

(c) The medical liability insurance carrier for the physician or office practice has been consulted when there is any indication that the request for record is being made by the attorney for the purpose of evaluating a potential legal action against the physician.

1.05 Appropriate post-treatment and continuing care instructions should be provided to patients, and should be documented in the record. It is preferable that such instructions be provided in writing, particularly when the instructions are part of a formal treatment plan.
Commentary:
There is a growing number of large medical liability judgments and awards arising from claims where defendant physicians failed to produce documented evidence of appropriate discharge or post-treatment continuing care instructions. Although most patients are provided with specific instructions before they leave the physician's office, documentation of such advice or warnings is seldom incorporated into the patient's record or, more importantly, provided to patients in writing. Some practice settings that use routine written discharge/continuing care instruction forms require that patients sign the form, a copy of which is retained in the medical record.